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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/929,597	08/13/2001	Todd K. Whitehurst	AB-126U	9184

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EXAMINER	
MACHUGA, JOSEPH S	
ART UNIT	**PAPER NUMBER**
3762	7

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/929,597	WHITEHURST ET AL.	
	Examiner	Art Unit	
	Joseph S. Machuga	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 3, 7-18 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 7-18 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Response to Arguments

1. Applicant's arguments filed Jan 7, 2004 have been fully considered but they are not persuasive. To summarize, the amendment adds to independent claims 1 and 17 the limitation that the stimulator is in or adjacent to the "ventral commissure." Since the claim language is written in such broad terms by the inclusion of the language "adjacent to" any stimulator located on the spine column would meet this limitation. More over, Silverstone 6161044 places the stimulator adjacent the lateral spinothalamic tract which is very close to the ventral commissure and therefore would clearly meet the limitation that the stimulator is "adjacent to" the ventral commissure. For these reasons applicant's arguments are not deemed persuasive.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of Silverstone #6161044.

Schulman et al discloses an implantable micro-stimulator system used to decrease pain. The system includes one or more nerve stimulators implanted adjacent a selected nerve. The system can also include at least one implantable sensor that senses a physical property of the patient and then provides appropriate feedback to an external device. Not disclosed by this reference is placing the electrode in or adjacent to the ventral commissure.

Silverstone teaches that the lateral spinothalamic tract is a know pathway for pain impulses and that stimulation along the pathways that carry those impulses can relieve pain (column 1, lines 58-67 and column 2 lines 1-10.) This region is near or "adjacent to" the ventral commissure.

It would have been obvious to one of ordinary skill in the art to place a nerve stimulator in Schulman et al's system adjacent the lateral spinothalamic tract to reduce pain as taught by Silverstone. Such a location would also be "adjacent" the ventral commissure and therefore the limitations of the claim would be provided for.

3. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of Silverstone as applied to claim 1 above, further in view of Zilber #3822708.

Zilber discloses an implant placed adjacent to the spinal cord. The reference teaches that a frequency of 5-200 Hz is effective in reducing pain.

Given this teaching, it would have been obvious to one of ordinary skill in the art to operate the stimulator of the proposed combination at a frequency of 5-200 Hz given Zilber's teaching that this helps reduce pain. The frequency as recited in method claims 3 would therefore be provided for since the reference teaches operating the stimulator both above and below 100Hz.

4. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926)) in view of Silverstone as applied to claim 1 above, further in view of King (6058331.)

King teaches that it is old and well know to place a stimulator next to the T8-L1 nerves to relieve pain in the feet or legs and next to the C5-C8 to relieve pain in the arms or hands (note column 5, lines 20+.)

Given this teaching it would have been obvious to one of ordinary skill in the art to place a stimulator implant of the proposed combination next to the T1-L1 nerves of the spine to relieve pain in the legs or feet, or next to the C5-C8 nerves of the spine to relieve pain in the arms or hands.

5. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926)) in view of Silverstone as applied to claim 1 above, further in view of Feler et al (6002964.)

Feler et al teaches that it is old and well know to place a stimulator next to the T10 –T12 nerves to reduce pain in the back or the pelvic region.

Given this teaching it would have been obvious to one of ordinary skill in the art to place a stimulator implant of the proposed combination next to the T10-T12 regions to relieve pain in the back or pelvic regions.

6. Claims 11 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926)) in view of Silverstone as applied to claim 1 above, further in view of MacDonald et al (#5776170.)

MacDonald et al teaches that it is old and well know to place a stimulator next to the C1-C8 nerves to relieve pain in the neck or head or cervix region (see column 3, lines 40-48.)

Given this teaching it would have been obvious to one of ordinary skill in the art to place a stimulator of the proposed combination next to the C1-C8 regions to relieve pain in the head, neck or cervix regions.

7. Claims 17, 18 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schulman et al (WO98/37926) in view of Silverstone as applied to claim 1 above, further in view of Schulman et al (5358514.)

Schulman et al (514) discloses that the implant should be around 10mm in length. Also, viewing Figures 1A, 1B and 1C if the implant is approximately 10 mm in length then the leads would be less that 150mm and within 150 mm of the nerve to be stimulated.

To make the implants of the proposed combination around 10mm and with leads in proportion to that and locate the device within 150mm of the nerve as disclosed by Schulman (514) would have been obvious would have been obvious to one of ordinary skill in the art since the smaller the device the easier it would be to implant.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on Monday-Friday; 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joseph S. Machuga
Examiner
Art Unit 3762

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700